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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/214,848 | 01/14/1999 | TERUAKI SEKINE | 1208/P502PCT | 8123 |

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| EXAMINER |
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CHOI, FRANK I

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 11/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/214,848

Applicant(s)

SEKINE, TERUAKI

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-27, 29 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-27, 29, 31-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 15-18, 29,33,35 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Koenig et al. for the reasons of record set forth in the prior Office Action and the further reasons below.

Koenig et al. expressly discloses compositions comprising autologous lymphocytes from an AIDS patient activated with IL-2 and OKT3 which activated autologous lymphocytes were resuspended in normal saline and human serum albumin and reinfused into the patient in doses of 28×10^9 , 12×10^9 and 13×10^9 for treatment of the patient's HIV infection falling within the scope of applicant's claims (Pg. 334-335).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205

USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978) and Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Applicant has made no showing that the autologous lymphocytes of the claimed invention are actually different from the autologous lymphocytes of the prior art. Clearly, Applicant has the ability to provide comparative data showing the differences as methods for differentiating lymphocytes are known in the art. See Koenig et al., pgs. 334-336, Methods. As such, Applicant's general argument that the amendment overcomes Koenig et al. is not sufficient to overcome the rejection herein.

Claims 12-27, 29, 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ochoa et al. (U.S. Pat. 5,443,983) in view of Rosenberg (US Pat. 4,690,915) and Melder et al. for the reasons of record set forth in the prior Office Actions in further view of the acknowledged prior art and Wallace et al. or the acknowledged prior art and Rooney et al. and the further reasons below.

Ochoa et al. (U.S. Pat. 5,443,983), Rosenberg (US Pat. 4,690,915, and Melder et al. were discussed in the prior Office Action and the same are incorporated herein.

Applicant acknowledges that T-cells are involved in cellular immunity against cancer and viruses (Specification, Pgs. 1, 2). Further, it is acknowledged that lymphocytes, including T-cells and NK cells, can be activated and stimulated by IL-2 and that lymphocytes can be activated and stimulated with IL-2, with or without CD3 antibodies, including against viruses, such as, EBV and CMV (Specification, pgs. 3,4).

Wallace et al. or Rooney et al. teach that T-cells activated with IL-2 are effective against EBV (See entire disclosure of each).

Applicant's arguments have been duly considered but they are deemed unpersuasive.

Applicant argues that one of ordinary skill in the art would not expect that autologous lymphocytes would be effective against viral infections based on the Nature Medicine article. However, the Nature Medicine article is only a single article, is limited to HIV and a single patient, and did appear to conclude that treatment of with autologous lymphocytes would not be effective in treating viral infections but only that there were a number of factors which could have contributed to the adverse result in the patient tested (Pg. 332). Further, the Nature Medicine article specifically indicated that adoptive transfer of human cytomeglovirus specific CTL clones has yielded encouraging results and that the HIV infected patient's clinical deterioration might have been more accelerated without the treatment (pgs. 332, 334).

Applicant argues that Rosenberg only mentions viral infections in passing and does not contain any data or teaching which prove and enable one skilled in the art to make and/or use the invention. However, this is not the test for enablement. See MPEP Sections 2164.01 and 2121.01. In any case, the prior art does enable one skilled in the art to make and/or use the invention in that the use of autologous lymphocytes are suggested in viral, autoimmune diseases and correction of immune-deficiency diseases and methods of activation of lymphocytes and

administration of the same are taught (See Rosenberg, Column 4, lines 17-55). Further, the prior art teaches that IL-2 stimulated lymphocytes are effective against HIV infected cells (See Melder et al., entire reference). In any case, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that the prior art fails to suggest autologous lymphocytes, however, Rosenberg (US Pat. 4,690,915) clearly suggests the use of autologous lymphocytes (Column 4, lines 17-18). Further, one of ordinary skill in the art would expect from the teachings of Melder et al. that the activated lymphocytes, since they are effective against cancer cells, would also be effective against viruses, including herpes group viruses.

Applicant argues that activated autologous lymphocytes cells used in the present invention are distinctly different from the NK lymphocyte cells and LAK cells. However, Applicant's makes not showing how this distinctness overcomes the rejection herein. In any case, one of ordinary skill in the art would expect that any other suitable immune cells, including T-cells, could be used (See Rosenberg, Column 15, lines 9-22, Rooney et al., Wallace et al.)

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Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

October 30, 2003



**S. MARK CLARDY
PATENT EXAMINER
GROUP 1200**

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